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Improving blood pressure control in primary care: The ImPress study.

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What is known on this topic:

- Hypertension is a leading antecedent to a range of chronic and complex conditions, including renal disease, cardiovascular conditions and stroke.
- Nurses in primary care are well positioned to support individuals to improve BP through the modification of lifestyle risk factors and adherence to evidence-based guidelines.
- Currently there is insufficient evidence of the effect of nurse led interventions on health outcomes, like hypertension in the primary care setting.

What this paper adds:

- This paper outlines the protocol for a trial to target general practice patients most at risk of a CVD event to improve blood pressure and reduce lifestyle risk.
- Health outcomes measures, including lifestyle risk factors, body mass index, medication adherence and blood pressure will be gathered at baseline, six and twelve months.
- This novel intervention utilises the GPN role to top of their scope of practice, directing proactive, tailored BP management towards a population at high risk of CVD.

Abstract

Background

Hypertension is a preventable factor for cardiovascular disease (CVD), the leading cause of death globally. When hypertension is present with tobacco smoking, poor nutrition, physical inactivity or excessive alcohol consumption risk of CVD is increased. Given the prolonged engagement and ongoing relationship with patients, general practice nurses (GPNs) are ideally situated to actively engage with patients about optimal blood pressure control and lifestyle risk reduction.

Objectives

This study will test the effectiveness of a GPN-led intervention to reduce blood pressure in adults with hypertension and high cardiovascular risk.

Design

A multi-site, cluster randomised control trial (RCT) where the general practice is the unit of randomisation.

Methods

General Practices (n=20) will be block randomised to the intervention or usual care group. Adults with hypertension and high cardiovascular risk will be identified through an audit of electronic medical records and invited to attend an assessment visit. Eligible consenting patients will be recruited to the study. The intervention involves three face-to-face consultations and two telephone consultations with the nurse to assess lifestyle risk and develop an action plan. An appointment with the general practitioner (GP) will optimise pharmacotherapy. The primary outcome is blood pressure (BP), with secondary outcomes of lifestyle risk factors; smoking, nutrition, alcohol and physical activity (SNAP) body mass

index (BMI) and medication adherence. Patients will have outcome measures evaluated at 6 and 12 months.

Discussion

ImPress is innovative in its proactive approach of identifying those at greatest risk of CVD and using the emerging role of the GPN to target care towards improved BP control. If successful, findings from this trial could enhance the nursing role, improve health outcomes, inform health policy and provide an evidence base from which to transform blood pressure management in general practice.

Trial Registration

This RCT has been registered with the Australian and New Zealand Clinical Trials Registry as ACTRN12618000169246

What is known on this topic:

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- Nurses in primary care are well positioned to support individuals to improve BP through the modification of lifestyle risk factors and adherence to evidence-based guidelines.
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- Health outcomes measures, including lifestyle risk factors, body mass index, medication adherence and blood pressure will be gathered at baseline, six and twelve months.
- This novel intervention utilises the GPN role to top of their scope of practice, directing proactive, tailored BP management towards a population at high risk of CVD.

1. Background

Hypertension causes more deaths and disease than any other biomedical risk factor (National Heart Foundation of Australia, 2016). While effective pharmacotherapy and treatment exists, many of the 1 billion people worldwide estimated to have hypertension struggle to maintain optimal blood pressure (Mills et al., 2016). Uncontrolled high blood pressure places individuals at greater risk of developing life limiting diseases including renal failure, cerebrovascular accident and CVD (Cadilhac et al., 2012). When hypertension is present in combination with other modifiable risk factors such as abnormal blood lipids, elevated blood glucose, tobacco use, obesity, alcohol consumption, physical inactivity and nutritionally inadequate diet, the absolute risk of a CVD event is further increased (Blood Pressure Lowering Treatment Trialists' Collaboration, 2014, Sundström and Neal, 2015). People who fall into this high risk group have the most to gain from improved blood pressure control.

Lowering blood pressure by as little as 1-2mmHg can reduce the morbidity and mortality associated with developing CVD (National Vascular Disease Prevention Alliance, 2012, Verdecchia et al., 2010). In addition, lifestyle modification can effectively delay or prevent the occurrence of hypertension, reduce existing high blood pressure and in some cases abolish the need for antihypertensive medication (National Heart Foundation of Australia, 2016). Given the global prevalence of hypertension and its impact on morbidity and mortality (Mills et al., 2016, Zhou et al., 2017), there is an opportunity to improve the management of BP within primary care.

There is growing emphasis internationally on providing health care in the community where people live. Historically, primary care has been largely delivered by GPs however, a growing team of multidisciplinary health professionals has emerged in this environment (Kringos et al., 2010, The Royal Australian College of General Practitioners, 2018). While models of primary care vary internationally, it usually represents the first point in which

individuals present their health issues for treatment and ongoing health management (Kringos et al., 2010). Despite the availability of effective pharmacotherapy and treatment guidelines, barriers to optimal hypertension management in primary care exist (Sundström and Neal, 2015). Sub optimal blood pressure control has been associated with therapeutic inertia, lack of structured self-management support and patient knowledge, beliefs and behaviours around antihypertensive medications (Khatib et al., 2014, Sundström and Neal, 2015). Drawing on the professional expertise of other members of the primary care team, such as nurses, has been associated with enhanced care delivery (Sullivan et al., 2016) and could assist in overcoming these barriers (Stephen et al., 2018a, Zwar et al., 2017).

The nursing workforce in general practice has grown significantly in recent decades along with international recognition that the role could be more fully utilised (Bauer and Bodenheimer, 2017, Halcomb et al., 2014, Merrick et al., 2014). Current models of general practice remain reactive, GP led care (Russell, 2018) with lack of role clarity, suboptimal collaboration and funding mechanisms contributing to the under-utilisation of nurses (Bauer and Bodenheimer, 2017, McInnes et al., 2015). Emerging evidence demonstrates nurse-led chronic disease management to be feasible and highly acceptable to consumers (Halcomb et al., 2015a, Halcomb et al., 2015b, Mahomed et al., 2012, Stephen et al., 2018a, Stephen et al., 2018b). Given their professional scope of practice and prolonged engagement with consumers, primary care nurses are ideally placed to provide team based blood pressure management and risk factor reduction initiatives (Halcomb et al., 2004, Halcomb et al., 2007b). While conceptually alluring, the true impact of nurse-led care on health outcomes such as blood pressure improvement remains uncertain (Authors own) (Halcomb et al., 2007b, Stephen et al., 2018b). Variability in intervention components, reported outcomes, methodological quality and sample size seen in previous RCTs eludes definitive conclusion (Authors own)(Halcomb et al., 2007a). Therefore, it is

timely to conduct a robust cluster RCT to provide evidence about the impact of this kind of intervention on health outcomes.

1.1 Aim/Hypothesis

The primary objective of the 'Improving blood pressure in Primary Care' (ImPress) RCT is to determine the effect of the intervention on blood pressure. Secondary objectives are to evaluate the interventions' impact on lifestyle risk factors; *smoking, nutrition, alcohol and physical activity* (SNAP), BMI and medication adherence. It is hypothesized that, at 6 and 12 months follow-up, patients with uncontrolled hypertension who receive the ImPress intervention will have; lower blood pressure, fewer lifestyle risk factors (SNAP), reduced BMI and improved medication adherence.

2. Methods

2.1 Study design and setting

This study is a multi-site cluster RCT. To prevent contamination between intervention and control groups, the unit of randomisation will be the primary care site (general practice). General practices will be eligible to participate if they employ at least one Registered Nurse, have computerised clinical software (Medical Director or Best Practice) and if both GP and the GPN are willing to participate. A registered nurse is a baccalaureate prepared nurse (or equivalent) who is registered with the Nursing and Midwifery Board of Australia (Nursing and Midwifery Board of Australia, 2016). Twenty general practices will be recruited across South Western Sydney and Illawarra / Shoalhaven based on their willingness to participate and adopt the intervention within their model of care. The trial will use CONSORT guidelines (Moher et al., 2012) to aid in transparency of reporting.

2.2 Randomisation

Practices will be assigned to the intervention or control group in block by a statistician independent to the research team. This block randomisation method will increase the probability of each group containing an equal number of participants (Efird, 2011).

2.3 Sample size

Intra-cluster correlation coefficients and design effects for the outcome measures of systolic BP, diet score, physical activity score and BMI will be calculated using data from the Health Improvement and Prevention study, (Fanaian et al., 2010). This study is a seminal investigation of cardiovascular disease in Australian general practice. The calculation is based on a predicted between person standard deviation of 8mmHg (Fanaian et al., 2010). This is a compromise between the high effect (14mmHg) seen in the pilot study (Authors own) and the clinically significant difference of 5mmHg, which would overly inflate the sample size.

The pilot study has demonstrated that 10 participants per practice is achievable and feasible within the available resources (Authors own). Therefore, the calculation has considered a cluster size of 10 and an intra-cluster correlation coefficient of 0.063. Using these figures, 154 participants across 15 practices would be required. However, allowing for 30% dropout / loss to follow up, a total sample of 200 patients across 20 practices will be sought. At this sample size, the study will also be sufficiently powered to detect a clinically significant difference in diet score (0.6 units), physical activity score (0.8 units) and BMI (2 units) and improved medication adherence as measured by the Hill-Bone Scale (Kim et al., 2000) and the Brief Medication Questionnaire (BMQ)(Svarstad et al., 1999).

2.4 Participant eligibility criteria

Patients will be eligible to participate if they are aged between 45 and 74 years, have a diagnosis of hypertension, are at high risk of a CVD event and have an office blood

pressure greater than140/90 mmHg at the assessment visit (National Heart Foundation of Australia, 2008, National Heart Foundation of Australia, 2016). This age group was selected to align with the Royal Australian College of General Practitioners guidelines on absolute cardiovascular risk (Royal Australian College of General Practitioners, 2015). Additionally, participants need to have actively attended the participating general practice 3 or more times in the last 2 years (Royal Australian College of General Practitioners, 2015). High CVD risk is defined as CVD risk greater than 15% or the presence of CVD as per the National Vascular Disease Prevention Alliance (2012). The CVD risk calculation is based on the combination of risk factors present and determines the probability of a CVD event within the next 5 years. Participants who have insufficient medical record data to calculate CVD risk, or with no recorded blood lipids results within the last 5 years, will be excluded unless data can be collected. Patients will also be excluded if they have insufficient English or impaired mental capacity which impacts their ability to consent and participate in the study or if they have a concomitant terminal diagnosis.

2.5 Patient recruitment

Participating GPNs will conduct a structured electronic search of practice medical records to identify eligible patients. As clinical auditing tools and software systems vary across general practices, the research team will offer technical support as required.

From the list of potentially eligible patients, fifty individuals will be mailed an invitation containing study information and details about attending an assessment appointment with the GPN. Following the invitation letter, GPNs will call potentially eligible patients to offer further information and also encourage participation opportunistically during routine visits. Flyers and notices displayed in waiting room and clinical areas will also be used to increase patient awareness of the study. If insufficient response is received from the first fifty potential participants after a four week period, a further fifty potential participants will be sent an invitation letter. Such recruitment has been successfully utilized in other trials

and was demonstrated to be feasible and acceptable in the pilot study (Thoma et al., 2010)(Authors own).

Potentially eligible patients will attend an assessment visit with the GPN to determine their eligibility and provide informed consent. If the office blood pressure exceeds 140/90mmHg at the assessment visit (National Heart Foundation of Australia, 2016) the patient will be invited to participate. Those patients who present for an assessment visit with a blood pressure less than 140/90mmHg, or who indicate that they do not wish to participate, will be thanked for their time and provided with written health information about cardiovascular health. Patient recruitment will continue across general practices until the desired sample size (n=200) is reached. Anticipated participant flow through the trial is depicted in Figure 1.

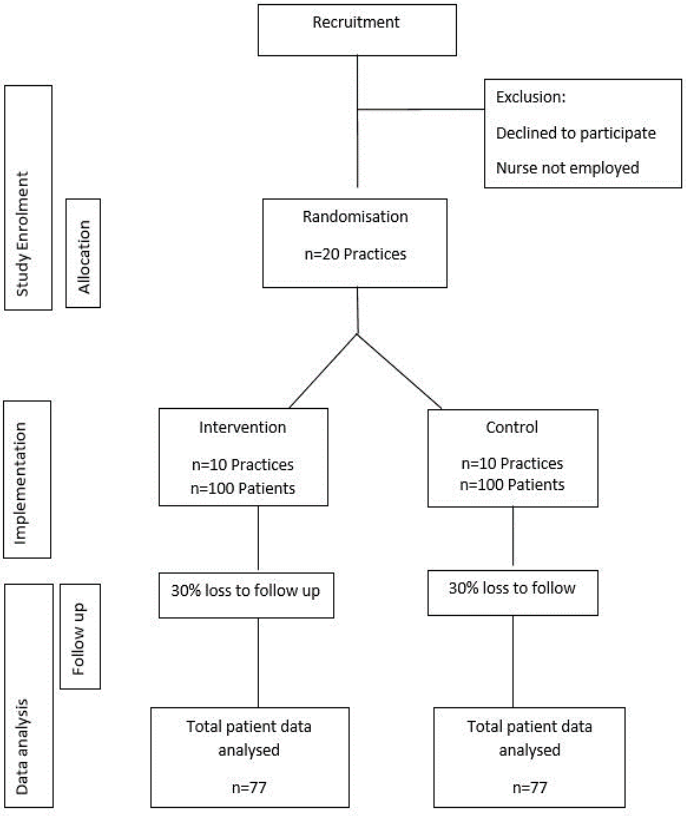

Fig 1 Predicted Patient Participant Flow

2.6 Intervention

ImPress aims to improve BP control for individuals at risk of CVD by combining a proactive care approach with the emerging role of the GPN. The intervention is based on the 5A's and motivational interviewing to bolster self-management support (Glasgow et al., 2006, Halcomb, 2017, Miller et al., 2008). The initial GPN consultation will record baseline BP, biometric measurements and lifestyle risks and serves as a foundation from which rapport and shared understanding is built. Subsequent visits will focus on individualised action planning in partnership with the patient, goal setting and feedback on progress (Figure 2). Nurses have been provided with print resources on smoking, nutrition, alcohol and physical activity to visually aid lifestyle discussions with the patients. GPs will reinforce lifestyle information and provide medication optimisation in line with Australian hypertension guidelines (National Heart Foundation of Australia, 2008).

Templates to structure each nursing assessment will be provided in hard copy and digital format. GPNs will be encouraged to collaborate with the participating GP(s) to share information around the nursing care being provided.

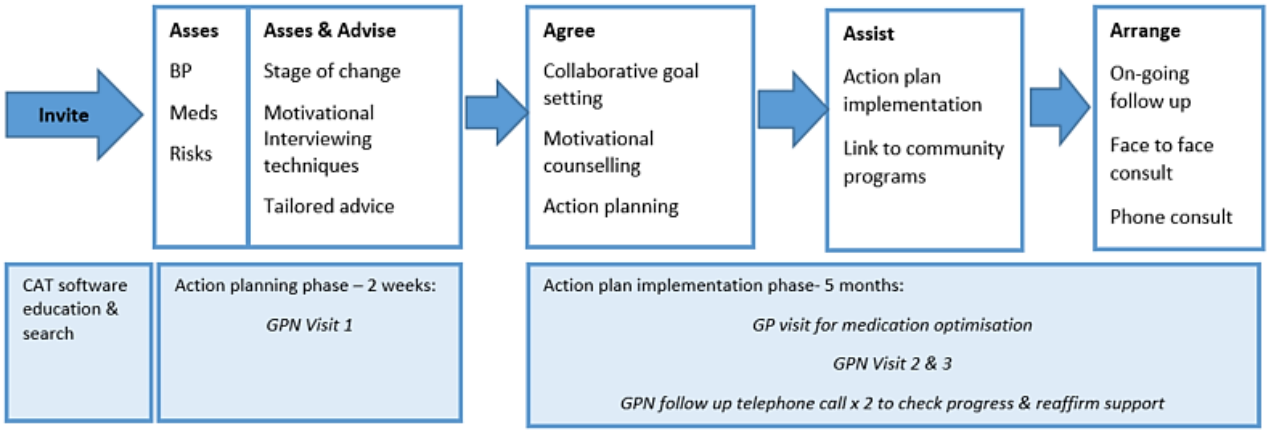

Figure 2 The ImPress Intervention

2.7 Pre-Intervention education

GPNs in the intervention arm will be reimbursed for attending a 1-day education session prior to the commencement of patient recruitment. Experts in the field of chronic disease management will deliver content on study rationale and procedures, data collection, blood pressure management protocol, motivational interviewing techniques and goal setting. This education format was piloted previously and viewed by participants as a vital preparatory step for intervention implementation (Authors own). Ongoing nurse mentoring and support will be provided by the trial co-ordinator throughout the study. The research team will conduct telephone support initially on a weekly basis then monthly as the intervention progresses.

2.8 Standard care

GPNs in control practices will receive a funded three-hour training session at the study commencement by the trial co-ordinator. Information will be provided on study recruitment, conducting medical record searches, data collection measures and accurate BP measurement (National Heart Foundation of Australia, 2016). Patients assigned to the control group will receive usual care from their general practice during the study period. Following the conclusion of the data collection, GPNs from the control group practices will receive a half-day hypertension management education session and lifestyle guideline resources.

2.9 Outcome assessment

Outcomes will be assessed for all participants at baseline, 6 and 12 months after recruitment. The primary outcome measurement, blood pressure, will be recorded by the GPN using an automated office blood pressure device. The specific devices used in each practice will be checked to ensure that they are up to date with calibration schedules. Whilst there is debate surrounding the appropriateness of various methods of BP measurement (Leenen and Myers, 2015, Myers et al., 2014), this method has been

chosen as it most closely resembles usual practice and so is practical and cost-effective. BMI will be calculated using the standardised method of dividing weight (in kilograms) by height (in metres squared)(National Heart Foundation of Australia, 2016). Both weight and height will be measured by the nurse using standard techniques.

The tools used to collect survey data will be provided to participating patients in the waiting room prior to the GPN visit. Patients self-reported smoking, nutritional, alcohol and physical activity will be collected using the Australian Bureau of Statistics Health Survey (Australian Bureau of Statistics, 2013). Medication adherence will be assessed using the Hill-Bone Compliance Scale (Kim et al., 2000) and the BMQ (Svarstad et al., 1999). The 10 item Hill-Bone Compliance Scale (Kim et al., 2000) measures sodium intake, appointment keeping and medication taking on a Likert scale with responses from 1 (Never) to 4 (all of the time). Additionally, the BMQ is a 9-item tool comprised of a 5 items on medication regime, 2 items on beliefs of drug efficacy and disadvantages and a 2 item recall section around remembering difficulties (Svarstad et al., 1999).

2.10 Data management

Data will be stored in the short term at the participating practice in a secure location before being collected by the research team. Once returned, paper data will be stored in locked filing cabinets at the University of XXXX and electronic data on password protected computers. In line with the Australian Code for the Responsible Conduct of Research (National Health and Medical Research Council, 2007), these data will be stored for 5 years following publication of findings. Findings will be presented in a way which ensures individual participants and general practices are non-identifiable. Only the researchers involved in this study will have access to the raw data.

2.11 Statistical analysis

Data will be entered into SPSS (IBM Corp, Released 2012) and checked for completeness and data entry errors. Subsequently, the data will be examined for differences between

primary (BP) and secondary outcomes (BMI, medication adherence and lifestyle risk factors). Variables between patients will be explored within and across practices using a linear mixed model. The intra-cluster correlation coefficient, or the measure of relatedness between the data (Killip et al., 2004) will be calculated and published to aid future research.

2.12 Ethics

Human Research Ethics approval for the conduct of this trial has been gained from the Human Research Ethics Committee of the University of XXXX prior to commencing recruitment and data collection (Approval No ###).

2.13 Dissemination strategy

Findings will be submitted for publication in relevant, high impact peer reviewed journals. Social media platforms such as Twitter and Facebook will be used to further amplify research impact globally to online communities. Results will also be of interest to clinical and academic audiences therefore the research team plan to disseminate findings at relevant professional conferences internationally. Participating patients, practices and key stakeholders will be informed of results in plain English via newsletters and presentations at local clinical and research meetings.

3. Discussion

Improving hypertension management in primary care is very important given the implications of unresolved high blood pressure. Targeting those most at risk, by selecting individuals at high CVD risk, represents an innovative proactive strategy rather than simply being reactive to adverse health outcomes. Utilising the GPN to direct the intervention capitalizes on their relationships with patients to achieve lifestyle risk reduction (Halcomb et al., 2004), while encouraging them to practice at the top of their scope of practice has the potential for economic benefits, improved job satisfaction and retention (Halcomb et al., 2018). Although utilizing the role of the GPN in this area is conceptually alluring, the

effectiveness of nurse-directed interventions upon health outcomes is not well established (Authors own). This study will provide robust evidence of the impact of a nurse-directed intervention for blood pressure management in high risk general practice patients. Results from this RCT could change the way in which hypertension care is organized and delivered in Australian general practice.

This study is underpinned by a robust theoretical foundation. Elements of the Chronic Care Model (Wagner et al., 1996) have been embedded into intervention design to foster self-management support and enhance delivery of targeted, person-centered BP management. Previous interventions have employed evidence based strategies namely the 5A's Framework (Zwar et al., 2015) and Motivational Interviewing (Ma et al., 2014, Song et al., 2014) to assist patients in self-management support. GPNs in the ImPress trial will be equipped to apply the 5A's in conjunction with Motivational Interviewing techniques to enhance their ability to set goals and support patients embarking on lifestyle behavior change.

ImPress also leverages a contextual advantage in terms of financial sustainability. Currently, nurse activity in general practices is supported by annual Australian Government funding (Australian Govenment, 2018). While a fee for service funding system operates in Australian primary care, moves towards block funding (McKittrick and McKenzie, 2018) and wider calls to reform to integrative, team orientated models could further enhance the nursing role (McInnes et al., 2016, Russell, 2018).

Despite these significant strengths, a trial of this nature comes with methodological challenges. Recruitment across 20 geographically dispersed sites could prove challenging given the well reported engagement, recruitment and retention issues associated with multi-center RCTs in primary care (Heal et al., 2018). Therefore, there is potential that predicted sample size may not be achieved. To mitigate this, sample size calculations

have allowed for a 30% drop out rate and extra support from the research team will be offered to practices experiencing difficulties with intervention implementation and delivery.

While research in general practice is necessary to improve service delivery and enhance evidence based patient care, barriers to participation have been identified. The Australian fee-for-service system, time pressures and poor financial incentives for research activities are regularly cited factors that influence participation refusal (Brodaty et al., 2013, Heal et al., 2018, McKinn et al., 2015). In an effort to overcome these barriers, ImPress has been designed to ensure that minimal financial, time and workload burdens are associated with intervention implementation and delivery. Education sessions, data collection and consultations undertaken by nurses will be reimbursed at regular intervals throughout the intervention.

To mitigate implementation issues and support problem solving, regular contact between clinicians and the research team will be maintained. Given the potential for variability between practice workplaces and styles, a process evaluation will be conducted at study conclusion to uncover the contextually specific barriers and enablers to the intervention.

True multidisciplinary primary care research is vital to enhance professional knowledge and patient care. This study is innovative in its approach to proactively managing a common, but clinically significant health problem in primary care. Results will inform health policy, clinical practice, professional education and models of multidisciplinary care in general practice.

Conflicts of interest

Nil.

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Ethical approval

This study was approved by the Human Research Ethics Committee of the XXXXX (Approval No. XXX).

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